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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/011,860	11/05/2001	Gust H. Bardy	032580.0042.CIP	6000

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT PAPER NUMBER

3766

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/011,860

Applicant(s)

BARDY ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-53 and 55-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-53 and 55-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 49-53, 55-60 and 63-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Scheiner et al. (2002/0147475).

Regarding claims 49-53 and 55-60, Scheiner shows a method comprising generating energy, storing the energy; delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform (i.e. unipolar pacing) of either positive or negative polarity having a peak voltage that is between approximately 25 V to approximately 50 V, between approximately 50 V to approximately 75 V, between approximately 0.1 V to approximately 100 V, and between approximately 0.1 V to approximately 25 V; a pulse width between approximately 1 millisecond and approximately 40 milliseconds, between approximately 2 milliseconds and approximately 40 milliseconds, between approximately 10 milliseconds and approximately 20 milliseconds, between approximately 20 milliseconds and approximately 30 milliseconds, and between approximately 30 milliseconds and approximately 40 milliseconds (Paras. [0030],[0042])

With respect to claim 63, Scheiner shows the energy is provided at a rate between approximately 20 and approximately 120 stimuli/minute (Paras. [0039],[0042]).

Regarding claims 64-69, the statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. In the aforementioned claims, there is no recitation of a method step of detecting the heart rate at or below 20 beats/minute, nor are there recitations of method steps of positioning the ICD at various location between particular ribs.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (2002/0147475) in view of Stein (4,498,478). Scheiner is as explained before. Although Scheiner fails to explicitly show the monophasic waveform shape. Attention is directed to Stein which shows that it is well known to utilize monophasic pacing pulses having a tilt between approximately 5% and 95% (Fig. 3) and that pacing pulse tilt is a function of the capacitor discharge which is ultimately dependent upon the capacitor used, the electrode tissue interface and the pulse width (Col. 6, lines 14-25). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform as taught by Scheiner with a monophasic pacing pulses having a tilt between approximately 5% and 95%, since it is well known in the art to utilize monophasic pacing pulses having a tilt between approximately 5% and 95% and because the tilt it is ultimately dependent upon the capacitor utilized, the electrode tissue interface and the pulse width.

Regarding claims 62, Scheiner and Stein disclose the claimed invention except for the monophasic waveform having a tilt of 50%. Scheiner and Stein teach that the pacing pulse tilt is a function of the capacitor discharge which is ultimately dependent upon the capacitor used, the electrode tissue interface and the pulse width. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize a monophasic waveform having a 50% tilt, since applicant has not disclosed that this particular tilt provides any criticality and/or unexpected results, it appears that the invention would perform equally well with any tilt such as the 5% to 95% tilt, taught by Scheiner and Stein for applying pacing pulses.

5. Claims 49 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al. (2002/0082658). Heinrich shows a method comprising generating energy, storing the energy; delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform of either positive or negative polarity having a peak voltage (Para. [0064]). As pointed out by applicants, the priority date of the Heinrich provisional application (60/252811) is not applicable to the 50 V peak voltage disclosed in the published application, but rather is applicable only to 100V peak voltage disclosed in the provisional application. Heinrich fails to show that the monophasic waveform has a peak voltage that is between approximately 25 V to approximately 50 V, and between approximately 50 V to approximately 75 V. It would have been obvious to one with ordinary skill in the art at the time the invention was made to optimize the monophasic waveform peak voltage as taught by Heinrich with monophasic waveforms having a peak voltage that is between approximately 25 V to approximately 50 V, and between approximately 50 V to approximately 75 V, since the peak voltage applied during a pacing pulse that will effectively pace the heart is dependent upon patient specific factors such as

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tissue impedance and it has long been held that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 456 (CCPA 1955); *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, (Fed. Cir. 1989), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, (Fed. Cir. 1997).

6. Claims 50-52, 55-60 and 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al. (2002/0082658) as evidenced by Heinrich et al. (60/252811).

Regarding claims 50-52, 55-59 and 60, Heinrich shows a method comprising generating energy, storing the energy; delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform of either positive or negative polarity having a peak voltage and pulse width (Para. [0064]). As pointed out by applicants, the priority date of the Heinrich provisional application (60/252811) is not applicable to the 50 V peak voltage disclosed in the published application, but rather is applicable only to 100V peak voltage disclosed in the provisional application. Since applicants have introduced the provisional application as evidence of non-enablement of the 50 V peak voltage, it is fair for the examiner to utilize the same evidence to show that the pacing pulse width in fact comprises 50 milliseconds. The provisional application more clearly illustrates that the pacing pulse width is delivered for 50 milliseconds in Fig. 4 and A-2 (immediate recharging) and that the pulse width has a duration of the entire 50 milliseconds since the recharging takes place immediately. Heinrich fails to show that the monophasic waveform has a peak voltage that is between approximately 0.1 V to approximately 100 V, between approximately 0.1 V to approximately 25 V, and between approximately 25 V to approximately 50 V; a pulse width that is between approximately 1 ms to approximately 40 ms,

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between approximately 2 ms to approximately 10 ms, between approximately 10 ms to approximately 20 ms, between approximately 20 ms to approximately 30 ms and between approximately 30 ms to approximately 40 ms. It would have been an obvious to one with ordinary skill in the art at the time the invention was made to optimize the monophasic waveform peak voltage and pulse width as taught by Heinrich with monophasic waveforms having a peak voltage that is between approximately 0.1 V to approximately 100 V, between approximately 0.1 V to approximately 25 V, and between approximately 25 V to approximately 50 V; a pulse width that is between approximately 1 ms to approximately 40 ms, between approximately 2 ms to approximately 10 ms, between approximately 10 ms to approximately 20 ms, between approximately 20 ms to approximately 30 ms and between approximately 30 ms to approximately 40 ms since the peak voltage and pulse width applied during a pacing pulse that will effectively pace the heart is dependent upon patient specific factors such as tissue impedance and it has long been held that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 456 (CCPA 1955); *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, (Fed. Cir. 1989), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, (Fed. Cir. 1997).

With respect to claim 63, Heinrich shows the energy comprises a monophasic waveform provided at a rate of between approximately 20 and 120 stimuli/minute (the pacing pulses are separated by 1500 ms, which is equivalent to a rate of 40 stimuli/minute) (Para [0067]).

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Regarding claim 64, Heinrich shows the intended use that the waveform is provided when the heart rate is less than approximately 20 beats/minute (asystole greater than 3 seconds is equivalent to 20 beats/minute or less) (Para [0067]).

Regarding claims 65-69, see Figs. 6-9 where Heinrich shows the intended use of the implantable defibrillator being subcutaneously positioned between the third and fifth ribs, fourth and sixth ribs, sixth and eighth ribs, eighth and tenth ribs and tenth and twelfth ribs.

7. Claims 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al. (2002/0082658) in view of Stein (4,498,478). Heinrich is as explained before. Although Heinrich fails to explicitly show the monophasic waveform shape. Attention is directed to Stein which shows that it is well known to utilize monophasic pacing pulses having a tilt between approximately 5% and 95% (Fig. 3) and that pacing pulse tilt is a function of the capacitor discharge which is ultimately dependent upon the capacitor used, the electrode tissue interface and the pulse width (Col. 6, lines 14-25). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform as taught by Heinrich with a monophasic pacing pulses having a tilt between approximately 5% and 95%, since it is well known in the art to utilize monophasic pacing pulses having a tilt between approximately 5% and 95% and because it is ultimately dependent upon the capacitor utilized, the electrode tissue interface and the pulse width.

Regarding claims 62, Heinrich and Stein disclose the claimed invention except for the monophasic waveform having a tilt of 50%. Heinrich and Stein teach that the pacing pulse tilt is a function of the capacitor discharge which is ultimately dependent upon the capacitor used, the electrode tissue interface and the pulse width. It would have been obvious to one with ordinary

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skill in the art at the time the invention was made to utilize a monophasic waveform having a 50% tilt, since applicant has not disclosed that this particular tilt provides any criticality and/or unexpected results, it appears that the invention would perform equally well with any tilt such as the 5% to 95% tilt, taught by Heinrich and Stein for applying pacing pulses.

Response to Arguments

8. Applicants' arguments with respect to claims 49-53 and 55-69 have been considered but are moot in view of the new ground(s) of rejection. Applicants' arguments regarding the pulse widths of the monophasic pacing pulse shown in Heinrich et al. (2002/0082658) have been addressed above in Paragraph 6.

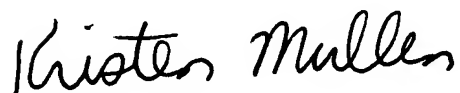
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kristen Mullen
Patent Examiner
Art Unit 3766

kdm